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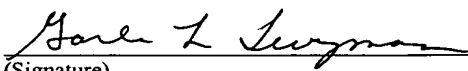
THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: 3738
Confirmation No.: 9094
Application No.: 10/044,031
Invention: **Purified Submucosa Graft Material**
Applicant: Stephen F. Badylak
Filed: January 11, 2002
Attorney
Docket: 3220-69262
Examiner: Unknown

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231

on November 13, 2002


(Signature)

Garla L. Twyman
(Printed Name)

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

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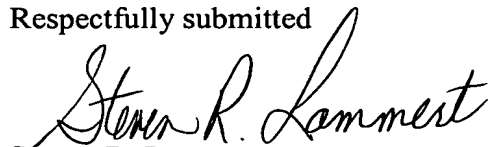
This statement is filed in the application identified above pursuant to 37 C.F.R. § 1.56. Some of the references disclosed herein were cited in U.S. Patent Application No. 08/916,490 (now U.S. Patent No. 6,206,931) to which the captioned application claims priority. Accordingly, copies of the references cited in the '931 patent are not provided with this Information Disclosure Statement. Patent references BD through DD and references AX through AZ were not cited in the '931 patent and copies of these references are transmitted herewith.

No representation is intended that a complete search has been made of the prior art or that no better art references than listed below are available. The filing of this Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in §1.56(b).

None of the cited art is believed to disclose or suggest the invention recited in the claims of the above-identified application. It is therefore believed that the claimed invention is patentably distinguishable over these references.

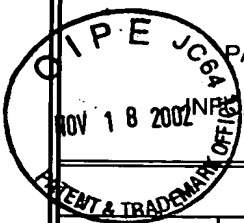
Applicants believe that no fees are required with this statement. The Assistant Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to our Deposit Account No. 10-0435, with reference to our matter 3220-69262. A duplicate copy of this paper is enclosed for that purpose.

Respectfully submitted



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Registration No. 27,653
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317-231-7258



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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
3220-69262SERIAL No.
10/044,031APPLICANT
Badylak, et al.FILING DATE
January 11, 2002GROUP
Unknown

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*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if
	AA	3,810,473	May 14, 1974	Cruz et al.			
	AB	4,578,067	Mar. 25, 1986	Cruz			
	AC	4,902,508	Feb. 20, 1990	Badylak, et al.			
	AD	4,956,178	Sept. 11, 1990	Badylak, et al.			
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	AF	5,275,826	Jan. 4, 1994	Badylak, et al.			
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	AK	5,480,424	Jan. 2, 1996	Cox			

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	AL	WO 90/00395	Jan. 25, 1990	PCT			
	AM	WO 93/05798	Apr. 1, 1993	PCT			
	AN	WO 96/25179	Aug. 22, 1996	PCT			
	AO	WO 96/31157	Oct. 10, 1996	PCT			
	AP						

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices; Dec. 1987, Prepared by Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, Center for Devices and Radiological Health, and Center for Veterinary Medicine.
AS	Hodde, J. P. et al.; "Glycosaminoglycan Content of Small Intestinal Submucosa: A Bioscaffold for Tissue Replacement" Tissue Engineering, vol. 2, No. 3, 1996, pp. 209-217, XP002063373.
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AU	Cobb, M.A. et al.; "Histology After Dural Grafting With Small Intestinal Submucosa", Surgical Neurology, vol. 46, No. 4, 1996, pp. 389-394, XP002071883.
AV	Vaught, J.D. et al.; "Detrusor Regeneration in the Rat Using Porcine Small Intestinal Submucosal Grafts: Functional Innervation and Receptor Expression", The Journal of Urology, vol. 155, No. 1, 1996, pp. 374-378, XP002071884.
AW	Baldry, M.G.C. and Fraser, J.A.L.; Disinfection with Peroxygens; United Kingdom; pp. 91-116.
AX	"Biological Evaluation of Medical Devices-Part 1: Guidance on Selection of Tests," American National Standards, Inc., ANSI/AAMI 10993-1, pp. 13-14 (1994).
AY	"Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices," ASTM F 748-91, pp. 198-201 (1991).
AZ	"Guidance Document for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Intra-Articular Prosthetic Knee Ligament Devices," USFDA Center for Devices and Radiological Health, pp. 1-40 (1987).

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

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APPLICANT

Badylak, et al.

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	BA	5,507,810	Apr. 16, 1996	Prewett, et al.			
	BB	5,733,337	Mar. 31, 1998	Carr, et al.			
	BC	5,782,914	July 21, 1998	Schankereli			
	BD	4,978,668	Dec. 18, 1990	Babbs et al.			
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	BJ	5,516,533	May 14, 1996	Badylak et al.			
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	BL						
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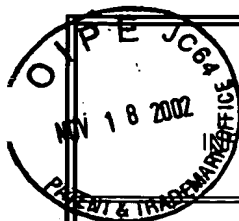
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APPLICANT
Badylak, et al.

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GROUP
Unknown

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	CA	5,573,784	Nov. 12, 1996	Badylak et al.			
	CB	5,641,518	June 24, 1997	Badylak et al.			
	CC	5,645,860	July 8, 1997	Knapp, Jr. et al.			
	CD	5,695,998	Dec. 9, 1997	Badylak et al.			
	CE	5,711,969	Jan. 27, 1998	Patel et al.			
	CF	5,753,267	May 19, 1998	Badylak et al.			
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	CH	5,762,966	June 9, 1998	Knapp, Jr. et al.			
	CI	5,866,414	Feb. 2, 1999	Badylak et al.			
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	CK	5,955,110	Sept. 21, 1999	Patel et al.			

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	CL						
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	CP						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

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				APPLICANT Badylak, et al.			
				FILING DATE January 11, 2002		GROUP Unknown	

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	DA	5,968,096	Oct. 19, 1999	Whitson et al.			
	DB	5,997,575	Dec. 7, 1999	Whitson et al.			
	DC	6,087,157	July 11, 2000	Badylak et al.			
	DD	6,171,344	Jan. 9, 2001	Atala			
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	DK						

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DL							
DM							
DN							
DO							
DP							

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